REMARKS

Claims 1-8, 10-17, and 19-23 remain pending in the application upon entry of the present amendment. Claims 1, 8 and 10 have been amended. Claims 19-23 have been added.

As stated in the Office Action, Claims 1-9 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification, while allegedly being enabling for the methods for treating pain associated with diabetic neuropathy using gabapentin or pregabalin with [2-(1*H*-indol-yl)-1-methyl-l-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethylester [R-(R*,S*)], does not reasonably provide enablement for methods of treating any chronic pain such as causalgia, surgery or traumatic pain, HIV infection, multiple sclerosis, hypothyroidism and anticancer chemotherapy. It is further stated in the Office Action that the specification allegedly does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate with the scope of the present claims.

In order to expedite prosecution, Applicants have amended the claims to define a method for treating diabetic neuropathy by administering to a patient in need of treatment a synergistic combination of an NK_1 receptor antagonist selected from [2-(1*H*-indol-yl)-1-methyl-l-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethylester [R-(R*,S*)] and (2-methoxy-benzyl)-((2S,3S)-2-phenyl-piperidin-3-yl)-amine and a GABA analog selected from gabapentin and pregabalin. Applicants reserve the right to file subsequent applications to cover the cancelled subject matter. Applicants respectfully submit that the data provided in the application provides support for the claimed method of treatment and synergistic combination set forth in the canceled claims. Accordingly, Applicants respectfully submit that they are entitled to a breadth of protection commensurate with the contribution made to the art by the invention and thus, that the scope present claims are sufficiently enabled. Accordingly, for the above-reasons Applicants respectfully submit that claims 1-8, 10-17 and 19-23 satisfy 35 U.S.C. § 112, first paragraph, and Applicants request that the Examiner remove the rejection on this ground.

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Field et al. (Field I) and Field et al. (Field II). Reconsideration of the rejection under 35 U.S.C. § 103(a) is as unpatentable over Field I in view of Field II is respectfully requested.

In the Office Action it is stated that Field I teaches that NK_1 receptor antagonist compound [2-(1*H*-indol-yl)-1-methyl-l-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] is used in animal models for neuropathic pain and that Field II teaches that the GABA analogs compounds gabapentin and pregabalin are also useful for treating neuropathic pain. The amended claims of the present application are directed to a method for treating diabetic neuropathy comprising administering to a patient in need of treatment an effective amount of a synergistic combination of a NK_1 receptor antagonist selected from [2-(1*H*-indol-yl)-1-methyl-l-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and (2-methoxy-benzyl)-[(2S,3S)-2-phenyl-piperidin-3-yl]-amine and a GABA analog selected from gabapentin and pregabalin. Applicants submit that one of ordinary skill in the art, aware that both the NK_1 antagonist [2-(1*H*-indol-yl)-1-methyl-l-(1-phenyl-ethylcarbamoyl)-ethyl]-carbamic acid benzofuran-2-ylmethyl ester [R-(R*,S*)] and that both gabapentin and pregabalin had utility in the treatment of pain, would, at best, expect to see an additive effect by using the agents in combination. However, Applicants have unexpectedly found that the claimed combination gives a greater than additive effect, that is a synergistic effect. This can clearly be seen from the Figures presented in the description which provide a comparison of the calculated additive effect and in the observed greater synergistic effect. Such an effect could not have been predicted and one of ordinary skill in the art, aware of the prior art, would not have been motivated to test the combination with a reasonable expectation of success (i.e., of achieving synergy). The observation of synergy is, in itself, an unexpected result. Thus, Applicants respectfully submit that the presently pending claims are not obvious in light of the cited art.

Accordingly, Applicants respectfully submit that the supra-additive or synergistic effect is both unexpected and surprising and that Applicants have provided an advance and potential pain therapies. Accordingly, Applicants respectfully submit that the data provided in the application demonstrates that the presently claimed in invention is not obvious in light of either Field I or Field II. Neither of the references, either individually or in combination, teach the claimed invention. Reconsideration is respectfully requested.

In view of the present amendment and foregoing remarks, reconsideration of the rejection and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with the communication to our deposit account number 23-0455.

Respectfully submitted,

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